REMARKS

Claims 19-38 are currently pending in the application.

THE INVENTION

Applicants' invention is an apparatus for implanting a therapeutic agent within a tissue wall. It includes an elongate flexible body, a delivery chamber coupled to the distal end and having a space for carrying a plurality of sequentially positioned pellets comprising a therapeutic agent, and a port for releasing the therapeutic agent. It also includes an actuator coupled to the delivery chamber and capable of sequentially driving pellets containing the therapeutic agent through the port. The distal end is adapted to penetrate a tissue wall so that the therapeutic agent can be delivered and implanted within the tissue wall.

The apparatus can also include a control mechanism coupled to the actuator, which provides control of the actuator, and a steering mechanism for turning the distal end of the apparatus, allowing the user to selectively guide the device through a body lumen. It can also include a lever-action handle coupled to the control mechanism.

The distal end can be dimensionally adapted to allow for transluminal delivery entry into the interior of a patient's heart. It can also include a plunger for driving the therapeutic agent from the delivery chamber, such as a threaded plunger for advancing into the delivery chamber in response to a rotating action, and a ratchet assembly for allowing delivery of the therapeutic agent in discrete amounts.

The delivery chamber can be substantially cylindrical, and adapted to receive and store the therapeutic agent in the form of pellets, for instance, minispheres or pellets having a pointed shape.

THE CITED ART

Wappler (U.S. Pat. No. 2,269,963; "Wappler")

U.S. Pat. No. 2,269,963 to Wappler discloses a device for implanting small solid bodies into the human body, particularly rod-like "radium seeds." The device is generally pistol-like, with a flesh-piercing point and a plunger for discharging the pellets.

As pointed out on page 3 of the action, Wappler fails to disclose that the device has a flexible body, as required by the present claims.

Campbell *et al.* (U.S. Pat. No. Re. 34,936; "Campbell")

Campbell discloses a system for implanting a solid marker in an animal, which includes a rigid hollow tube (col. 4, lines 10-17) with a sharp distal tip to penetrate the skin of the animal, and a plunger to engage the marker and eject it beneath the animal's skin.

Dragan (U.S. Pat. No. 4,457,712; "Dragan")

This reference discloses a dental syringe with a barrel and a plunger, intended to extrude root canal resin into a root canal. The device is generally pistol-like, and includes a reservoir for holding the resin, and a plunger, ratchet pawl and a needle for dispensing the resin.

THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claims 20-27 and 29-38 as defining subject matter that would have been obvious to one of ordinary skill in the art over Wappler and Campbell. Each of the claims include the limitation that the elongate body be flexible. None of the references cited discloses a flexible body.

As noted on page 3 of the action, Wappler does not disclose that the elongate body be flexible, and the Campbell reference is relied on for this limitation. The action directs the reader to Fig. 9 and col. 4, lines 10-17 of Campbell, noting that the body can be made from plastic resin.

Campbell discloses a device for implanting a solid identification marker underneath the skin of an animal, and the section referred to in the action notes that instead of the exemplary embodiment of stainless steel construction,

> tube 20 can also be made from other rigid FDA approved materials, such as Utem®, manufactured by General Electric. Also, as aforenoted, sleeve 25 and plug 24 can be integrally formed by injection molding a plastic resin about the entrance opening of tube 20. Also, the sleeve and plug may be formed of rigid materials other than plastic.

Col. 4, lines 11-17, emphases added.

Indeed, review of Fig. 9 (and also Fig. 13) reveals that the parts corresponding to reference numerals 20 and 25 would need to be rigid in order for the device to function. Tube 20 is a hypodermic-type needle with a sharp beveled tip, and sleeve 25 appears to be a supporting structure. If tube 20 were made of a flexible material, it would be very difficult to use the device to puncture the skin of the animal and inject the marker. Campbell does not disclose that the device has a flexible body, and instead requires that tube 20 be made from a rigid material. To interpret the reference otherwise ignores the function and purpose of the disclosed device.

Where neither Wappler nor Campbell disclose or suggest that the devices have an elongate flexible body, their combination cannot render the device obvious.

Claim 28 was rejected in view of Wappler in combination with Dragan. This claim depends from claim 20, and also requires that the body be flexible. Wappler has been established as failing to disclose a flexible body. Dragan likewise fails to disclose that the

needle/nozzle is flexible. Where neither reference discloses or suggests an elongate flexible body, their combination cannot render such a device obvious.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721, Reference No.: 0506765.0016.

Respectfully submitted,

Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111-2950
Tel: 617-261-3100
Fax: 617-261-3175

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